JAN - 9 2001

K 000560

14. Summary of Safety and Effectiveness Information:

510(k) SUMMARY

Submitter	Synthes (USA) 1690 Russell Road Paoli, PA 19301
Company Contact	Bonnie Smith (610) 647-9700
Name of the Device	Synthes (USA) Resorbable Tack System
Predicate Device	MacroPore, Inc. MacroSorb FX Tacks
Device Description	The Synthes Resorbable Tack System consists of resorbable tacks and accessory instruments, which are additional components of the Synthes Resorbable Fixation System. Resorbable tacks are available in Ø1.5 and 2.0 mm diameters and in lengths ranging from 4 - 8 mm. Synthes Resorbable Tacks are manufactured from 70:30 poly (L/DL-lactide). Synthes Resorbable Tacks are provided pre-sterilized by gamma radiation. They are not intended to be resterilized by the user.
Intended Use	Synthes Resorbable Tack System is intended for fractures of the craniofacial skeleton including, but not limited to, comminuted fractures of the naso-ethmoidal and infraorbital areas, comminuted fractures of the frontal sinus wall, and midfacial fractures; and reconstructive procedures of the midface or craniofacial skeleton. Synthes Resorbable Tack System is not intended for use in the mandible or other full load-bearing situations, for areas with active infection or for patient conditions including blood supply limitations, insufficient quantity or quality of bone, or latent infections.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 9 2001

Ms. Bonnie J. Smith
Senior Regulatory Affairs Associate
Synthes (USA)
1690 Russell Road
Paoli, Pennsylvania 19301

Re: K000560
Trade Name: Synthes (USA) Resorbable Tack System
Regulatory Class: II
Product Code: JEY
Dated: November 16, 2000
Received: November 22, 2000

Dear Ms. Smith:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic

Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. **Indications for Use**

Premarket Notification [510(k)]

INTENDED USE STATEMENT

510(k) Number (if known): K000560

Device Name: Synthes (USA) Resorbable Tack System

Indications

Synthes Resorbable Tack System is intended for fractures ~~of the craniofacial skeleton~~ including, but ~~not limited to~~, comminuted fractures of the naso-ethmoidal and ~~infraorbital areas, comminuted~~ fractures ~~of the frontal~~ sinus wall, and midfacial fractures; and reconstructive ~~procedures of the midface~~ or craniofacial ~~skeleton~~.

Contraindications

Synthes Resorbable Tack System is not intended for use in the ~~mandible or other~~ full load-bearing situations, for areas ~~with active~~ infection or for patient conditions ~~including~~ blood supply limitations, insufficient quantity or quality of bone, or latent infections.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_
(Per 21 CFR 801.109)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K000560